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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/589,537

08/16/2006

Klaus Abraham-Fuchs

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HARNESS, DICKEY & PIERCE, P.L.C.

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EXAMINER

SEOH, MINNAH L

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/589,537	Applicant(s) ABRAHAM-FUCHS ET AL.	
	Examiner MINNAH SEOH	Art Unit 3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>16 August 2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. This action is in reply to the Application filed on 16 August 2006.
2. Claims 1-7 were amended.
3. Claims 8-17 were added.
4. Claims 1-17 are currently pending and have been examined.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 3, 8, 10, 11, 13, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 3 and 8 recite “wherein the secondary criterion is assigned to the selection criterion in accordance with linguistically employed medical terms.” What does the term “linguistically employed” entail? Does this just mean that words are used? Appropriate clarification and correction is required.
- Claims 3 and 8 recite “classification algorithm.” What is being classified? Is it the criteria? Is it the patient data? What is the classification algorithm actually doing. Appropriate clarification and correction is required.
- Dependent claims 10, 11, 13, and 16 are also rejected.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 1-17 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

A claimed process is eligible for patent protection under 35 U.S.C. § 101 if:

"(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing. See Benson, 409 U.S. at 70 ('Transformation and reduction of an article 'to a different state or thing' is the clue to the patentability of a process claim that does not include particular machines. '); Diehr, 450 U.S. at 192 (holding that use of mathematical formula in process 'transforming or reducing an article to a different state or thing' constitutes patent-eligible subject matter); see also Flook, 437 U.S. at 589 n.9 ('An argument can be made [that the Supreme] Court has only recognized a process as within the statutory definition when it either was tied to a particular apparatus or operated to change materials to a 'different state or thing' '); Cochrane v. Deener, 94 U.S. 780, 788 (1876) ('A process is...an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing.').⁷ A claimed process involving a fundamental principle that uses a particular machine or apparatus would not pre-empt uses of the principle that do not also use the specified machine or apparatus in the manner claimed. And a claimed process that transforms a particular article to a specified different state or thing by applying a fundamental principle would not pre-empt the use of the principle to transform any other article, to transform the same article but in a manner not covered by the claim, or to do anything other than transform the specified article." (*In re Bilski*, 88 USPQ2d 1385, 1391 (Fed. Cir. 2008))

Also noted in *Bilski* is the statement, "Process claim that recites fundamental principle, and that otherwise fails 'machine-or-transformation' test for whether such claim is drawn to patentable subject matter under 35 U.S.C. §101, is not rendered patent eligible by mere field-of-use limitations; another corollary to machine-or-transformation test is that recitation of specific machine or particular transformation of specific article does not transform unpatentable principle into patentable process if recited machine or transformation constitutes mere 'insignificant post-solution activity.'" (*In re Bilski*, 88 USPQ2d 1385, 1385 (Fed. Cir. 2008)) Examples of insignificant post-solution activity include data gathering and outputting. Furthermore, the machine or transformation must impose meaningful limits on the scope of the method claims in order to pass the machine-or-transformation test.

It is also noted that the mere recitation of a machine in the preamble in a manner such that the machine fails to patentably limit the scope of the claim does not make the claim statutory under 35 U.S.C. § 101, as seen in the Board of Patent Appeals Informative Opinion *Ex parte Langemyr et al.* (Appeal 2008-1495),

Claims 1-17 are not tied to a particular machine or apparatus nor do they transform a particular article into a different state or thing, thereby failing the machine-or-transformation test.

Claims 1-17, as recited, are directed toward a method for (selecting participants) comprising the steps of (storing, assigning, evaluating, determining, selecting). As currently written the steps recited in claims 1-17 are not tied to a machine, much less a significant tie to a particular machine (i.e. computer/processor/server/etc.)

Claims 1-17 are therefore non-statutory under § 101. Appropriate correction is required.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by
Boru et al. (US 2002/0077853).

CLAIM 1 –

As per claim 1, Boru et al. disclose a method comprising:

- electronically storing patient data assigned to a patient (***a patient's physician enters data (answers) from a patient's medical record 103 (or other source) into computer see par. [0083] of Boru et al.***)
- assigning a secondary criterion to the selection criterion (***each search criterion in criteria array 511 having a non-zero value is compared, one at a time, with the corresponding search criterion see par. [0084] of Boru et al.***)
- electronically evaluating the patient data on the basis of the secondary criterion (***each search criterion in criteria array 511 having a non-zero value is compared, one at a time, with the corresponding search criterion see par. [0084] of Boru et al.***)
- determining, based on the electronic evaluation, a measure for fulfilling the selection criterion for the patient associated with the patient data (***search engine 100 generates a list 110 of the clinical trials (and optionally, corresponding abstracts) found in the database 101 that match the user's input data see par. [0080] of Boru et al.***)

- selecting the patient as a potential participant on the basis of the determined measure

Though not explicitly stated Boru et al., the final step of selecting a patient is implicit in the process of Boru et al. since Boru et al. discloses a method of providing a list of eligible clinical trials.

CLAIM 2 –

Boru et al. disclose the method of claim 1 above. Boru et al. further disclose:

- wherein the secondary criterion is assigned to the selection criterion in accordance with known medical correlations (*if abnormal liver function as indicated by bilirubin count...results in a patient being excluded from a clinical trial, these blood chemistry indicators are considered to be exclusionary criteria see par. [0028] of Boru et al.*)

CLAIM 3, 8 –

Boru et al. disclose the method of claim 1 above. Boru et al. further disclose:

- wherein the secondary criterion is assigned to the selection criterion in accordance with linguistically employed medical terms (*if abnormal liver function as indicated by bilirubin count...results in a patient being excluded from a clinical trial, these blood chemistry indicators are considered to be exclusionary criteria see par. [0028] of Boru et al.*)

- the patient data are evaluated on the basis of the secondary criterion with a classification algorithm (***each search criterion in criteria array 511 having a non-zero value is compared, one at a time, with the corresponding search criterion see par. [0084] of Boru et al.***)

Claim 8 is rejected for substantially the same reasons as claim 3.

CLAIM 4, 9, 10, 11 –

Boru et al. disclose the method of claim 1 above. Boru et al. further disclose:

- the secondary criterion is assigned to the selection criterion in accordance with nonmedical correlations concerning the medical study (***2. Location see Table 1 of Boru et al.***)

Claim 9, 10, and 11 are rejected for substantially the same reasons as claim 4.

CLAIM 5 –

Boru et al. disclose the method of claim 1 above. Boru et al. further disclose:

- a probability value of 100% or 0% is determined as the measure
- the patient selected as a potential participant is selected as an actual participant or is rejected (***if abnormal liver function as indicated by bilirubin count...results in a patient being excluded from a clinical trial, these blood chemistry indicators are considered to be exclusionary criteria see par. [0028] of Boru et al.***)

CLAIM 6, 12, 13, 14 –

Boru et al. disclose the method of claim 1 above. Boru et al. further disclose:

- a probability value except 100% and 0% is determined as the measure
- for the patient selected as a potential participant, a measure with a probability value of 100% or 0% is determined on the basis of other than the stored patient data (***selecting a scalar position within a predetermined range*** see ***par. [0042] of Boru et al.***)
- the patient selected as a potential participant is selected as an actual participant or is rejected

Though not explicitly stated Boru et al., the final step of selecting a patient is implicit in the process of Boru et al. since Boru et al. discloses a method of providing a list of eligible clinical trials.

Claim 12, 13, and 14 are rejected for substantially the same reasons as claim 6.

CLAIM 7, 15, 16, 17 –

Boru et al. disclose the method of claim 1 above. Boru et al. further disclose:

- wherein unstructured medical documents assigned to a patient are digitalized and stored as patient data ***a patient's physician enters data (answers) from a patient's medical record 103 (or other source) into computer*** see ***par. [0083] of Boru et al.***)

Claim 15, 16, and 17 are rejected for substantially the same reasons as claim 7.

CLAIM 8 –

Boru et al. disclose the method of claim 2 above. Boru et al. further disclose:

- wherein the secondary criterion is assigned to the selection criterion in accordance with linguistically employed medical terms (***if abnormal liver function as indicated by bilirubin count...results in a patient being excluded from a clinical trial, these blood chemistry indicators are considered to be exclusionary criteria see par. [0028] of Boru et al.***)
- the patient data are evaluated on the basis of the secondary criterion with a classification algorithm (***each search criterion in criteria array 511 having a non-zero value is compared, one at a time, with the corresponding search criterion see par. [0084] of Boru et al.***)

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINNAH SEOH whose telephone number is (571) 270-7778. The examiner can normally be reached on 9:00 AM - 4:00 PM Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/M. S./
Examiner, Art Unit 3686
November 18, 2009

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686